

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FILED

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CLERK US DISTRICT COURT
WESTERN DISTRICT OF TEXAS

BY

DEPUTY

REYNALDO MUNIZ, JR.,
Plaintiff,

-vs-

Case No. A-13-CA-451-SS

MEDTRONIC, INC. and MEDTRONIC
SOFAMOR DANEK USA, INC.,
Defendants.

ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled cause, and specifically Defendants Medtronic, Inc. and Medtronic Somafor Danek USA, Inc.'s Motion to Dismiss [#6], Plaintiff Reynaldo Muniz, Jr.'s Response [#14], and Defendants' Reply [#19]; Plaintiff's Motion for Extension of Time to File Response [#16]¹; and Plaintiff's "Motion to Supplement Evidence to Response to Defendants' Motion to Dismiss" [#20] and Defendants' Response [#23]. Having reviewed the documents, the governing law, and the file as a whole, the Court now enters the following opinion and orders.

Background

Plaintiff Reynaldo Muniz, Jr. filed this lawsuit in May 2013 after allegedly discovering in April 2013 that Defendant Medtronic's Infuse Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (the Infuse Device), which was implanted in Muniz during his spinal fusion surgery in December 2010, had caused excessive bone growth in his spine, resulting in various injuries and

¹This motion is GRANTED.

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damages. According to Muniz, his doctor implanted the Infuse Device in an off-label manner, and his doctor did so as a consequence of Medtronic's organized campaign to promote the Infuse Device for off-label use in violation of regulations promulgated by the Food and Drug Administration (FDA). In a seventy-seven page complaint, Muniz, through his lawyer, describes this campaign and a myriad of issues related to Medtronic and the Infuse Device. Finally, at page fifty-nine, Muniz's lawyer decides to describe the factual allegations specifically related to his client's case, and he also asserts a number of state law causes of action against Medtronic: (1) negligence and gross negligence; (2) negligence per se; (3) negligent misrepresentation; (4) products liability—manufacturing defect; (5) products liability—design defect; (6) products liability—failure to warn, inadequate warning, inadequate instructions; (7) breach of express warranty; (8) breach of implied warranty; (9) fraudulent misrepresentation and fraud in the inducement; and (10) constructive fraud.

Medtronic now, pursuant to Federal Rule of Civil Procedure 12(b)(6), moves the Court to dismiss Muniz's claims. Medtronic argues each of Muniz's claims are expressly preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), because they seek to impose state-law requirements on the design, manufacture, or labeling of the Infuse Device that are different from or in addition to the federal requirements imposed by the FDA. Moreover, Medtronic argues to the extent Muniz's claims are based on Medtronic's promotion of the Infuse Device for off-label uses and seek to enforce the FDCA provisions governing the promotion of medical devices for off-label uses, they are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and prohibited by the "no private

cause of action” clause of the FDCA, 21 U.S.C. § 337(a). In addition to being preempted, Medtronic contends Muniz’s claims are barred by the applicable Texas statutes of limitations and are otherwise legally inadequate.

Analysis

I. Motion to Dismiss

Federal Rule of Civil Procedure 8(a)(2) requires a complaint contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” FED. R. CIV. P. 8(a)(2). A motion under Federal Rule of Civil Procedure 12(b)(6) asks a court to dismiss a complaint for “failure to state a claim upon which relief can be granted.” FED. R. CIV. P. 12(b)(6). In deciding a motion to dismiss under 12(b)(6), a court generally accepts as true all factual allegations contained within the complaint. *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993). However, a court is not bound to accept legal conclusions couched as factual allegations. *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Although all reasonable inferences will be resolved in favor of the plaintiff, the plaintiff must plead “specific facts, not mere conclusory allegations.” *Tuchman v. DSC Commc’ns Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994). The plaintiff must plead sufficient facts to state a claim for relief that is facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. Although a plaintiff’s factual allegations need not establish the defendant is probably liable, they must establish more than a “sheer possibility” that a defendant has acted unlawfully. *Id.* Determining plausibility is a “context-specific task,” that must be performed in light of a court’s “judicial experience and

common sense.” *Id.* at 679. In deciding a motion to dismiss, courts may consider the complaint, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, such as documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

Muniz’s seventy-seven page complaint could never be described as “a short and plain statement of the claim showing that the pleader is entitled to relief,” and the Court grants Medtronic’s motion to dismiss on this basis alone. Muniz’s lawyer spends over fifty pages of the complaint discussing in extraordinary detail: the history of the Infuse Device; Medtronic’s alleged unlawful off-label promotion scheme; Medtronic’s profit figures over the last decade; various whistleblower lawsuits; corporate integrity agreements; shareholder’s derivative suits; regulatory actions by the FDA; congressional investigations; the history of the bone graft as used in spinal fusion surgery; an exhaustive retelling of how the Infuse Device worked its ways through the FDA’s PMA process; a detailed accounting of the public literature and research studies conducted on the Infuse Device; the testimony of former Medtronic employees regarding off-label promotion; and so on and so forth. Apparently, Muniz’s counsel fails to comprehend how to write a complaint in federal court because he has turned the pleading stage into the summary judgment stage, complete with his attempt at establishing an evidentiary record. This effort is entirely premature and is not appropriate at this phase of a lawsuit.

The Court does not have the time or patience to read counsel’s novel, and identify the precise issues relevant to whether the plaintiff has actually stated a claim that would survive a Rule 12(b)(6) motion to dismiss. The task is to write “a short and plain statement of the claim” as required by the federal rules, and it must allege sufficient facts to state a claim for relief that is facially plausible as

required by the Supreme Court in *Iqbal* and *Twombly*. In its motion to dismiss, Medtronic has raised legitimate arguments concerning express and implied preemption, and the Court is aware of the divide sweeping through both federal and state courts on these precise issues. Moreover, this case would appear to possibly entail statute of limitations concerns. Therefore, Muniz's amended complaint should be specifically pleaded in a way that would allow the Court to make sense of his claims in the context of both these preemption and statute of limitations questions. In other words, to state a plausible claim upon which relief can be granted, Muniz's amended complaint must both avoid preemption and not be time-barred.

Therefore, the Court GRANTS Medtronic's motion to dismiss without prejudice to re-filing a motion to dismiss in the event Muniz files an amended complaint. Muniz shall have twenty days from entry of this order to file an amended complaint.

II. Motion to Supplement Evidence

Further demonstrating his lack of understanding of the current stage of litigation, Muniz's counsel has filed a "Motion to Supplement Evidence to Response to Defendants' Motion to Dismiss" [#20]. The Court, however, is completely unconcerned with the evidence at this point in time. The evidence—and its truth or falsity—has nothing to do with whether a complaint is properly pleaded so as to survive a 12(b)(6) motion. Furthermore, Muniz's counsel seeks "to alert the Court to new evidence he just received from Dr. Michael Floyd concerning the condition of [Muniz's] health due to Medtronic Infuse Device cage used in his surgery," and attaches a medical report describing Muniz's supposed health ailments. *Id.* at 1. Not only is this "evidence" completely irrelevant at this point in the case, the Court imagines counsel's client would prefer this private information be filed under seal rather than broadcast to the public by his lawyer. The Court DENIES Muniz's motion

to supplement the evidence, and orders the Clerk to SEAL the "Motion to Supplement Evidence to Response to Defendants' Motion to Dismiss" [#20].

Conclusion

Accordingly,

IT IS ORDERED that Defendants Medtronic, Inc. and Medtronic Somafor Danek USA, Inc.'s Motion to Dismiss [#6] is GRANTED without prejudice to refiling a motion to dismiss Plaintiff Muniz's amended complaint if he files one;

IT IS FURTHER ORDERED that Plaintiff Muniz shall have TWENTY (20) days from entry of this order to file an amended complaint or this case will be closed;

IT IS FURTHER ORDERED that Plaintiff's Motion for Extension of Time to File Response [#16] is GRANTED;

IT IS FURTHER ORDERED that Plaintiff's Motion to Supplement Evidence to Response to Defendants' Motion to Dismiss [#20] is DENIED;

IT IS FURTHER ORDERED that the Clerk shall SEAL Plaintiff's Motion to Supplement Evidence to Response to Defendants' Motion to Dismiss [#20].

SIGNED this the 20th day of March 2014.



SAM SPARKS
UNITED STATES DISTRICT JUDGE